

REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars:

1. Amendments and Support for Same

By the Response, claims 1-18 have been amended to more particularly point out and distinctly claim the subject matter of the invention. New claims 19-44 have been added to further complete the scope of protection to which Applicant is entitled. No new matter has been added. Accordingly, claims 1-44 are respectfully submitted for consideration, of which claims 1, 10, 21, 30, and 39 are independent.

Independent claim 1 has been amended to incorporate all of the features of original claim 10. Accordingly, claim 1 is directed to apparatus for predicting bone fracture risk, wherein the image analysis means performs shape and texture analysis of the DXA image to generate an image data set which is representative of aspects of the shape of the body part and the structure of bone within the body area covered by the image. Support for the amended features of claim 1 can also be found in, e.g., paragraph bridging pages 6 and 7 of the original specification.

Independent claim 10 parallel amended claim 1, but is directed to apparatus for measuring the progression of a disorder which affects the shape and/or trabecular structure of bone in a patient. Support for this amendment can be found in, e.g., original dependent claim 15.

New independent claim 21 has been added to cover apparatus for predicting a risk of osteoarthritis for a patient. Support for claim 21 can be found in, e.g., the second paragraph of page 9 of the original specification, wherein it is stated that although the present invention is principally directed to predicting fracture risk, it may also be applied for use with other disorders, including osteoarthritis.

New independent claim 30 has been added to cover apparatus for measuring non-pathological changes in a subject associated with age, gender, body mass index and/or genetics. Support for claim 30 can be found in, e.g., original dependent claim 17.

New independent claim 39 has been added to cover apparatus for quantifying deformation of a proximal femur of a patient. Support for claim 39 can be found at least in, e.g., line 15 of page 9 of the original specification.

Dependent claims 13-15, 22-24, and 31-33 parallel amended dependent claims 2-4, respectively.

Features in original claim 16 are now recited in amended dependent claims 11-12, which depend from claim 10.

No new matter has been added. Approval and entry of the amendments are respectfully requested.

2. Claim rejections under 35 U.S.C. §112, 2<sup>nd</sup> paragraph

With respect to the rejection of claim 18, Applicant has amended claim 18 as dependent claim, which depends from independent claim 10. The original claimed features of claim 18 have been cancelled. In view of the amendments and arguments set forth above, Applicant respectfully requests reconsideration and withdrawal of the §112, 2<sup>nd</sup> paragraph, rejections of claim 18.

3. Claim rejections under 35 U.S.C. §101

With respect to the rejection of original claim 4 under 35 U.S.C. §101, Applicant respectfully traverses the rejection at least for the reasons set forth below.

Initially, Applicant notes that the feature of original claim 4 are now recited in apparatus claims 5-6, 16-17, 25-26, 34-35, and 40-41.

According to the specification, An Active Shape Model (ASM) is an image processing model which can be used to analyze shapes which have common features, but

which are subject to natural variation, such as a human body part. An ASM is a mathematical model which can be used to quantify differences in the shape of a body part, for example the proximal femur, between an OP patient, and a control subject.

Applicant respectfully submits that ASM is not the principle idea of the presently claimed invention. Instead, ASM is a tool (i.e., a model) that is applied by the image analysis module, which is configured to analyze aspects of the DXA image, such as recited in claims 5, 16, 25, 34, and 40, for example. Moreover, ASM is also known to one skilled in the art to be useful in other applications in the field of image analysis.

Further, Applicant respectfully asserts that it is common to seek patent protection for an apparatus configured to perform a function, and that there is no requirement for Applicant to claim a software algorithm, inasmuch as there is no requirement for an invention to be recited as a software algorithm when mathematical techniques, such as Fourier Transform and statistical analysis techniques, for example, are implemented in a hardware module.

In view of the amendments and arguments set forth above, Applicant respectfully request reconsideration with withdrawal of the §101 rejection.

4. Rejections under 35 U.S.C. §103(a)

With respect to the rejection of claims 1-5, and 12-18 under 35 U.S.C. §103(a) as being unpatentable over Mazess (WO 94/06351), in view of Gregory ("Hip Fracture, Morphometry and Geometry", April 2002), and with respect to the rejection of claims 6-11 under 35 U.S.C. §103(a) as being unpatentable over Mazess and Gregory and further in view of Giger (US 5,931,780), Applicant respectfully traverses the rejection at least for the reason that Mazess, Gregory, and Giger, combined or separately, fail to teach, disclose, or suggest all of the limitation recited in the rejected claims.

With regard to Mazess, while this reference relates to the application of morphometric analysis to the results of a DXA scan, Mazess does not teach, disclose, or suggest image analysis of an image generated from data elements obtained from the scan.

In particular, with the method of Mazess, the data elements obtained during the scan are never actually assembled to generate an image of the scanned body part. Instead, the data

is processed through a series of stages which involve deriving histograms from selected data elements and “rebinning” the data elements to ultimately derive values for various characteristic geometric properties of the scanned body part, such as the anterior and posterior height of individual vertebra.

In contrast with Mazess, an important aspect of the present invention is that the apparatus does not simply analyze data obtained from a DXA scan. Rather, a DXA image of the body area is produced from the results of the DXA scan, and the image analysis module analyzes this image, specifically by performing shape and texture analysis of the image, to generate a data set which is representative of the shape of the body part and the structure of the bone within the body area.

Thus, Mazess does not teach, disclose, or suggest a module configured to produce a DXA image of a body part, or an image analysis module configured to perform shape (and texture) analysis of the DXA image to generate an image data set, as required by the presently claimed invention.

Applicant respectfully submits that, as acknowledged by the Examiner, Mazess makes suggestion, disclosure, or teaching of texture analysis.

With regard to Giger, the texture analysis discussed in Giger relates to the application of a Fast Fourier Transform to image data within pre-determined region(s) of interest identified in a digitized radiographic image of a body part. The placement of these region(s) of interest with respect to features in the radiographic image is of key importance in order to obtain repeatability, and to avoid distortion of the results due to the presence of, for example, overlapping edges, bowel gas, and soft tissue folds.

Applicant respectfully asserts that it is not obvious how such analysis of Giger could be incorporated with the process of morphometric analysis disclosed in Mazess. In this respect, as discussed above, Mazess relates to deriving values for various characteristic geometric properties of the scanned body part, through analysis of data obtained from a scan. As discussed above, at no stage is this data of Mazess presented in the form of an image which depicts the overall appearance of the body part.

Moreover, the results of the analysis of Mazess do not provide any information about the relative positions of different features in the image. In the absence of any depiction of the

overall appearance of the body part to illustrate the relative positions of different features, it is not clear how a region of interest could be identified from the data elements obtained by the apparatus of Mazess, in order to allow the texture analysis techniques disclosed in Giger et al to be applied.

Accordingly, Applicant respectfully submits that it would not have been obvious to one of ordinary skill in the art at to combine the teaching of Mazess with that of Giger and/or Gregory to arrive at the presently claimed invention. More particularly, as Mazess is deficient of the features of independent claims 1 and 10, as well as independent claims 21, 30, and 39, as discussed above, and as Giger and Gregory fail to cure the deficiencies of Mazess, the reliance on Mazess, Gregory, Giger, combined or separately, the obviousness rejections of claims 1-18 are improper.

More generally, with respect to Applicant's claimed invention, in order to improve prediction quality by combining different methods of analysis, additional information must be gained from each form of analysis. Although disorders affecting bones such as osteoporosis and osteoarthritis can be indicated by many factors, many of these factors are highly correlated and add relatively little information. In the present case, the applicant has found that bone shape and the internal structure of bones, as analyzed by shape and texture analysis of a DXA image of a body part, provide statistically independent measures that are indicative of such disorders, which can thus be combined to improve the performance of the apparatus. However, there is nothing in the available prior art to suggest that these two forms of analysis would provide statistically independent measures indicative of such disorders, and thus that they could be combined with any expectation of achieving improved results. Accordingly, Applicant respectfully submits that, without the benefit of hindsight, there would be nothing to motivate a person of ordinary skill in the art to apply texture analysis in combination with shape analysis as in the presently claimed invention.

The requirements for establishing a *prima facie* case of obviousness, as detailed in MPEP § 2143 - 2143.03 (pages 2100-122 - 2100-136), are: first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference to combine the teachings; second, there must be a reasonable expectation of success; and, finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations.

Further, according to MPEP §2141(I), Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Moreover, according to MPEP §2141(II), when applying 35 U.S.C. §103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole;

(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined.

In view of the amendment and arguments set forth above, Applicant respectfully requests the Examiner to follow tenets A-D in relying on Mazess, Giger, and Gregory in the obviousness rejections. Further, Applicant respectfully requests reconsideration and withdrawal of the §103(a) rejection of claims 1-18.

## 5. Conclusion

In view of the amendments to the claims, and in further view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is requested that claims 1-18, as well as new claims 19-44, be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the Applicant's representative, the Examiner is invited to contact the undersigned at the numbers shown.

Further, while no fees are believed to be due, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4525.

Respectfully submitted,

/Donald R. Studebaker/

Donald R. Studebaker

Registration No. 32,815

Studebaker & Brackett PC  
1890 Preston White Drive  
Suite 105  
Reston, Virginia 20191  
(703) 390-9051  
Fax: (703) 390-1277  
don.studebaker@sbpatentlaw.com